UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,527	10/02/2003	A.K. Gunnar Aberg	559P021	9335

7590 02/28/2005

Kevin S. Lemack
Nields & Lemack
Suite 7
176 E. Main Street
Westboro, MA 01581

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/677,527	ABERG, A.K. GUNNAR	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/2/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-14 ARE PRESENTED FOR EXAMINATION

Applicant's Information Disclosure Statement filed January 2, 2004 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449, the Examiner has considered the cited references.

Use of Trademarks

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The use of the trademarks "Regurin®" (e.g., specification at page 1, penultimate line), "Ditropan®" and "Detrol®" (both in the present specification at page 2, last sentence of the third paragraph) have been noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology. Thus, *for example*, "Regurin®" should be amended to read ---"REGURIN® (trospium chloride)---. Appropriate correction of the above is required.

Claim Objection

Claim 10 is objected to because of the following informality:

The term "patients" at line 1 is inconsistent in tense with "patient" at line 3. Appropriate correction is required.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pancreatitis (claim 10) or a disorder belonging to the group consisting of urolithiais and cholelithiasis (claim 11), does not reasonably provide enablement for the general treatment of a patient suffering from the above disorders where the objective for such treatment is not specified. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The present claims lack a recitation of a therapeutic objective to be achieved through the administration of trospium or a pharmaceutically acceptable salt thereof to a patient suffering from either pancreatitis or a disorder belonging to the group consisting of urolithiais and cholelithiasis. Therefore, the claims encompass the treatment of the host for *any* therapeutic purpose. The art, however, is currently unaware of any agent, or combination of agents, which is effective for treating all disease conditions, i.e., a panacea. Lacking knowledge of such, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that all disease conditions could be treated in a patient suffering from either pancreatitis or a disorder belonging to the group consisting of urolithiais and cholelithiasis. Given that the art fails to recognize, and Applicant has failed to demonstrate, that all disease conditions could be treated in the claim defined patients, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention.

Suggestion for Overcoming This Rejection

Applicant should amend claims 10 and 11 in the following manner in order to overcome the present rejection:

"10. A method for treating pancreatitis in mammal patients suffering therefrom ~~from acute pancreatitis~~, while avoiding...".

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

I The expressions "while avoiding the concomitant liability of adverse cardiac side effects" (claim 1), "while avoiding the concomitant liability for arrhythmogenicity" (claim 10), "while avoiding the concomitant liability of adverse cardiac side effects" (claim 12) and "while avoiding the concomitant liability of cardiac arrhythmias" (claim 13) fail to particularly point out the source of the liabilities that are avoided such that one skilled in the art would be apprised of whether or not a particular instance of trospium administration was within or outside the scope of the present claims.

II "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention

meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (MPEP 2173).

The term "about" in the expression "about 1mg to 240 mg per day" (claim 7) is a relative term which renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Because the term "about" would invite subjective interpretations of whether or not a particular dosage rate is included by or excluded from the present claims, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims fail to meet either the tenor or express requirements of 35 U.S.C. § 112, second paragraph and are properly rejected.

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. § 102, a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genetech, Inc.,* 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue,* 766 F2d531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily

function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Ulshöfer et al. (Clin. Drug Invest., cited by the Examiner) who teach a method of treating urodynamically verified motor urge incontinence which comprises administering trospium chloride, 15 mg three times daily for 28 days (i.e., 45 mg. per day) (see, for example, the abstract at page 563). The authors report that trospium chloride was administered as a coated tablet (page 565, section bridging cols. 1-2 headed "Drugs") which is indicative that a carrier is present in addition to trospium chloride.

The teaching of 45 mg/day is within the claimed dosage ranges of "from about 1 mg to 240 mg per day" (claim 7) and "from 10mg to 60mg per day" (claim 8). "[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated' if one of them is in the prior art." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing In re Petering, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (emphasis in original).

Ulshöfer et al. do not expressly disclose "avoiding the concomitant liability of adverse cardiac side effects" (claim 1). However, because the same drug is administered to the same host for the same purpose as in the present claims, such is deemed to be an inherent characteristic of the method of Ulshöfer et al.

Claims 6 and 10-14 Would Not Have Been Obvious

None of the cited references teach or suggest the presently claimed methods for treating pancreatitis or a disorder belonging to the group consisting of urolithiais and cholelithiasis.

Also, while Ulshöfer et al., as referenced above, teaches a method of treating of treating urodynamically verified motor urge incontinence, i.e., smooth muscle hyperactivity (present claims 12 and 13) which comprises administering trospium chloride, 15 mg three times daily for 28 days, the authors fail to teach that the patient population "has a higher than normal propensity for cardiac arrhythmias" (present claim 6), "suffering from Long QT syndrome" (present claim 12) or "predisposed to cardiac arrhythmias" (present claim 13). While such patients *may* have been generally suggested by the authors, a conclusion of obviousness would not be proper here because in the present specification at pages 13-15, Applicant has demonstrated an unexpected, practical advantage for trospium, as compared to other anticholinergic agents useful for urinary incontinence, which would overcome any presumption of obviousness that could be advanced by the Examiner. Namely, Applicants have demonstrated that trospium chloride does not cause a statistically significant prolongation of the QTc interval, as compared to other anticholinergic agents, i.e., terodiline, oxybutynin and tolterodine, thus indicating that trospium chloride would unexpectedly not place individuals of the present claims, e.g., those having a higher than normal

propensity for cardiac arrhythmias, at risk for suffering from an adverse effect of anticholinergic therapy for urinary incontinence such as cardiac arrhythmia.

The references cited on the attached form PTO-892 and not relied on are included to show the general state of the art.

None of the claims are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

February 22, 2005